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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,296	08/22/2003	Szu-Min Lin	ASP-5010	9226

27777 7590 09/25/2006

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EXAMINER

CHORBAJI, MONZER R

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 09/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/646,296	LIN ET AL.	
	Examiner	Art Unit	
	MONZER R. CHORBAJI	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/2/03:1/12/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This general action is in response to the application filing date of 08/22/2003

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-7 and 9-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Cummings (EP 0 373 201 B1).

Regarding claim 1, Cummings discloses a vapor hydrogen peroxide sterilization method for treating medical items (page 2, lines 45-50) that includes the following: placing articles into the chamber (page 2, lines 47-48), reducing pressure in the chamber to a first pressure that is above hydrogen peroxide vapor pressure and below atmospheric pressure (page 4, lines 24-27), introducing a sterilant as a mist into the chamber (page 5, lines 35-42) and diffusing the mist through the chamber into contact with the articles (page 5, 28-31).

Regarding claims 2-3, Cummings discloses generating vapor hydrogen peroxide from a solution of hydrogen peroxide and water (page 4, lines 24-41).

Regarding claims 4-6, Cummings teaches that the first vacuum pressure is at least 5 Torr, or 15 Torr, or 30 Torr below atmospheric (page 4, lines 24-27, the mm Hg unit in Cummings is equivalent to the Torr unit and 1 atmosphere is equal to 760 mm Hg or 760 Torr. Clearly, 5 mm Hg vacuum is below 5 Torr, or 15 Torr, or 30 Torr).

Regarding claims 7 and 9-10, Cummings teaches the following: sterilizing articles (page 2, lines 45-50), sterilizing the interior of the chamber (page 5, lines 54-56) and removing residual hydrogen peroxide from the chamber (page 6, lines 5-9).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cummings (EP 0 373 201 B1) as applied to claim 7 and further in view of Jacobs et al (U.S.P.N. 5,785,934).

Cummings tests the efficacy of the vapor hydrogen peroxide sterilization method by inoculating coupons with 10^6 Bacillus stearothermophilus (pages 6-7) prior to sterilization. Cummings further teaches sterilization cycles of 4 or 8 or 16 minutes (page 7). Cummings fails to teach inoculating stainless steel blades with 10^6 Bacillus stearothermophilus. Jacobs teaches inoculating stainless steel scalpel blades with Bacillus stearothermophilus (col.30, lines 49-53). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify Cummings testing method by adding 10^6 Bacillus stearothermophilus inoculated stainless steel blades as taught by Jacobs in order to guarantee the sterility of surgical devices so that no post-surgery infections occur.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Cummings et al (U.S.P.N. 4,956,145) and Childers et al (5,492,672) both sterilize medical instruments in a chamber where hydrogen peroxide vapor is applied where a first pressure vacuum is above sterilant vapor pressure yet below atmospheric pressure.


8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R. CHORBAJI whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 9:00-5:30.

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9. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, GLADYS J. CORCORAN can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MRC 


GLADYS JP CORCORAN
SUPERVISORY PATENT EXAMINER